

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dodic et al.

Serial No.: 10/518,347

Examiner: N. Grazier

Filing Date: December 17, 2004

Art Unit: 1626

For: *Phenoxyalkanonic Acid Derivatives as HPPAR Activators*

Commissioner for Patents

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RESPONSE TO RESTRICTION REQUIREMENT

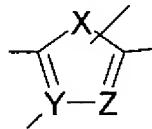
Sir:

This paper is submitted in response to the Restriction Requirement mailed July 14, 2006.

The Examiner states that the instant application contains multiple groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1, and requires Applicants to elect a single invention.

Applicants provisionally elect, with traverse, the following group:

Group IV: drawn to compounds of formula I wherein R¹, R², R³, R⁴, R⁵, R⁶, R⁷, R⁸, R⁹, R¹⁰, n and y, are as defined in claim 1, without limitation, and



the Het ring: is pyrazolyl.

Applicants also identify claims 1-11, 13-20, 22, 25, and 26 (all or in-part) as claims readable on the elected group.

The Examiner states that the instant application contains Markush practice and does not meet the unity of invention criteria under PCT Rules 13.1 and 13.2 because 1) the core structure is not the unifying criteria and 2) the variables do not belong to a “recognized class of chemical compounds in the art to which the invention pertains,” citing MPEP §1850(B). Applicants agree that the instant application contains Markush practice. However, Applicants disagree with the Examiner’s assertion that the core [common] structure is not the unifying criteria. As stated in MPEP §1850(III)(B) “Markush Practice,” in pertinent part, the “special technical feature” of Rule 13.2 shall be considered to be met when the [chemical] alternatives are of a similar nature. [C]hemical compounds shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; OR
- (B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

It appears the Examiner agrees that the compounds of Formula (I) all have a common property as required in (A). Therefore, it appears that the Examiner is stating that the compounds do not share a significant structural element as required under (B)(1), thus is applying the other criteria of (B)(2) wherein the alternatives must belong to a recognized class of chemical compounds. Applicants respectfully submit that the compounds of the instant invention do share a special technical feature that meets the unifying criteria of MPEP §1850(III)(B) by fulfilling the criteria of (A) and (B)(1) as noted above. The application of (B)(2) relating to the alternatives belonging to a recognized class of chemical compounds is not required.

MPEP §1850(III)(B) states that “significant structural element is shared by all of the alternatives” refers to cases where compounds share a common chemical structure which occupies a large portion of their structures. The Examiner states that “[t]he special technical feature is *phenoxy acetic acid*” (emphasis added in the original) and that “[u]nity of invention is [therefore] lacking because the core is not novel.” Applicants respectfully submit that this is not the proper application of Rule 13.2 as it relates to Markush practice. The Examiner has selected phenoxy acetic acid as the common structure of the instant invention. Applicants submit that the common structure is much larger than phenoxy acetic acid.

MPEP §1850(III)(B) provides, “[t]he [common] structural element may be a single component or a combination of individual components linked together.” In the instant invention, the common structure, as shown in the generic Formula (I), is not only the single phenoxy acetic acid moiety. Rather, it is a combination of individual components linked together. More specifically, the phenoxy acetic acid moiety is linked at the phenyl by a methylene linker to a substituted nitrogen atom, which is further linked directly, or by a methylene linker, to an optionally substituted 5-membered heterocyclic ring containing at least one heteroatom selected from O, S, or N, which is further linked to an optionally substituted phenyl. Thus, the compounds of the instant invention share a common structure that is a combination of individual components linked together, and the common structure occupies a large portion of their structures. Therefore, the compounds of the instant invention share a special technical feature and meet the requirements for unity of invention under PCT Rule 13.2. In light of the above arguments, Applicants respectfully request withdrawal of the restriction requirement.

The Examiner has listed thirteen groups, and states that each group is an individual invention. The Examiner further states that the claims should be

limited to “a product, a process for the manufacture of said product, or a method of use” (emphasis in the original) because the claims do not relate to a single general inventive concept under PCT Rule 13.1. Groups listed as I to X are all compounds or “products” and groups listed as XI to XIII are all “uses” of the “products” of several of groups I to X. The Examiner seems to be stating, *inter alia*, that the products and the use of those products are more than one invention. However, the Examiner cites 37 CFR 1.475 (b) which clearly states, in pertinent part, that different categories of inventions will be considered to have unity of invention if the claims are drawn to combinations of categories including a product and a process of use of said product (i.e. a product and a method of use of that product). Thus, the Examiner’s requirement that the claims be limited to a product, a process, or a method of use is improper, and the requirement for restriction among “product” groups I to X and “use” groups XI to XIII should be withdrawn.

The Examiner requires Applicants to elect a single invention and a single compound as a result of a lack of unity of invention among claims. Applicants have made a provisional election of a single invention, with traverse, as stated above. However, the Examiner’s requirement for the election of a single compound seems to be unfounded. Applicants respectfully submit that it is unclear whether the Examiner is **(a1.)** requiring the election as a restriction to a single species for lack of unity under PCT 13.1 and 13.2; or **(a2.)** attempting to require an election of species under U.S. restriction practice of MPEP §800 et seq.; or **(a3.)** requesting a provisional election of species for purposes of examination derived from 37 CFR 1.141 and 1.146. In the attempt to further prosecution, Applicants respond to **(a1.), (a2.), and (a3.)** below.

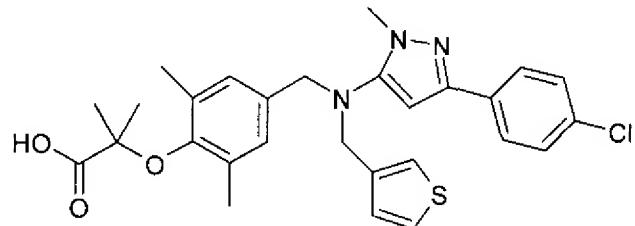
(a1.) The Examiner requires an election of species as a restriction among the disclosed species for lack of unity under PCT Rules 13.1 and 13.2 (presumably within the elected Group from above) by asserting that the individual

species lack unity of invention. Applicants respectfully disagree. Applicants refer the Examiner to MPEP §1850(III)(B) "Markush practice" and the arguments stated above relating to the compounds of the instant invention sharing a special technical feature. For such reasons stated above, Applicants submit that the species of the instant invention meet the requirements for unity of invention under PCT Rules 13.1 and 13.2. Therefore, Applicants respectfully request that the election requirement for purposes of restriction among species be withdrawn.

(a2.) The Examiner has requested an election of species pursuant to MPEP §800 *et seq.* The Applicant respectfully reminds the Examiner that the instant application is a national stage application filed under 35 U.S.C. §371. As stated, in pertinent part, in MPEP §1893.03(d), "[e]xaminers are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 USC §371." Hence, if an election for purposes of restriction among species is required, PCT Rules 13.1 and 13.2, not M.P.E.P. §800 *et seq.*, shall apply. Applicant has responded above in section (a1.) to an election for purposes of restriction among species under PCT Rules 13.1 and 13.2. Additionally, U.S. restriction practice under MPEP §800 *et seq.* does not apply to the instant application. Therefore, Applicant respectfully requests withdrawal of the election of species requirement.

(a3.) The election of species required by the Examiner may be a request for a provisional election for purposes of examination derived from, for example, 37 CFR. 1.141 and 1.146. Applicants believe that this is the only election that may be proper in the instant application, rather than those described in (a1.) or (a2.) above. However, Applicants respectfully disagree that the election is required. Yet, to further prosecution, Applicant provisionally elects, with traverse, Example 4, also known as 2-[4-((5-(4-chloro-phenyl)-2-methyl-2H-pyrazol-3-yl]-

thiophen-3-ylmethyl-amino}-methyl)-2,6-dimethyl-phenoxy]-2-methyl-propionic acid, and having the structure:



Additionally, Applicants identify claims 1-7, 9-11, 13, 15-20, 22, 25, and 26 as claims readable on the elected species.

Applicant respectfully reminds the Examiner that any request for a provisional election of species in a national stage application filed under 35 U.S.C. §371 may only properly flow from 37 C.F.R. 1.141 and 1.146, and is not an election for purposes of restriction. Furthermore, the election is a provisional election that the Examiner may request, but is not required to, so long as the application meets the remaining requirements under 37 C.F.R. 1.141. Applicants believe that the instant application contains an allowable generic claim to all of the claimed species. Thus, the application meets all of the provisions of 37 CFR. 1.141. Since any restriction to an individual species in a national stage application must be based on lack of unity under PCT Rules 13.1 and 13.2, and not MPEP §800 *et seq.*, a provisional election of a single disclosed species under 37 C.F.R. 1.141 and 1.146 solely provides an aid for examination of the application rather than a restriction to the elected species. The instant application is a national stage application, the disclosed species do not lack unity under PCT Rules 13.1 and 13.2., and MPEP §800 *et seq.* do not apply. Applicants have provisionally elected a species for purposes of examination and identified the claims readable on the elected species. Therefore, Applicant